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ATTORNEY FOR PLAINTIFF
UNITED STATES OF AMERICA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BUTTE DIVISION

UNITED STATES OF AMERICA,	CR 13-04-BU-DLC
Plaintiff,	<u>RESPONSE TO</u>
vs.	<u>DEFENDANT'S</u>
PAUL DANIEL BOTTOMLEY,	<u>SENTENCING</u>
Defendant.	<u>MEMORANDUM</u>

Plaintiff, United States of America, by and through its counsel of record, Jessica T. Fehr, Assistant U.S. Attorney for the District of

Montana, hereby responds to the sentencing memorandum filed by the defendant on July 5, 2013. Sentencing in this matter is scheduled for July 12, 2013, at 11 a.m.

THE CHARGE

On April 24, 2013, the defendant, Paul Daniel Bottomley, pled guilty to a one count Information that charged misprision of a felony in violation of 18 U.S.C. § 4. The offense of conviction carries a maximum punishment of three years imprisonment, a \$250,000 fine, 1 year supervised release, and a \$100 special assessment. The advisory guideline range calculation contained within the presentence report is calculated at 12 to 18 months imprisonment. Neither party has lodged any objection to the presentence report as submitted. The United States has filed a motion for a downward variance for substantial assistance pursuant to U.S.S.G. § 5K1.1. The United States is recommending a one level reduction to an advisory guideline range of 10 to 16 months. The United States is requesting the Court impose a sentence of twelve months and one day incarceration to be followed by one year of supervised release and the \$100 special assessment.

RELEVANT FACTS

Paul Daniel Bottomley owned a company called Montana Health Care Solutions (MHCS) in Belgrade, Montana. MHCS was opened in 2008 and was sold to Rockley Ventures, Ltd., a division of Canada Drugs, Ltd., in October of 2010. While owned by Bottomley, MHCS imported and distributed misbranded and unapproved drugs from foreign countries to American physicians. Bottomley's conduct while the owner of MHCS was in direct violation of the Food, Drug, and Cosmetics Act (FDCA) of the United States.

Specifically, Bottomley as the owner of MHCS distributed what were classified as "new drugs" under 21 U.S.C. § 321(p) that required approval by the U.S. Food and Drug Administration (FDA) under 21 U.S.C. § 355 before they could be imported into the United States. The foreign prescription drugs distributed by Bottomley were not typically the versions that the FDA had approved for use in the United States, because, among other things, the drugs' labeling information did not conform to the FDA approved labeling for the United States versions. For example, the labeling for the foreign versions failed to contain the National Drug Code (NDC) numbers, which are part of the FDA

approved labeling for versions approved for use in the United States.

In addition, some of the drugs distributed by Bottomley contained non-English language labeling, including use and dosage instructions.

In October of 2010, Bottomley sold MHCS to Rockley Ventures, Ltd., a subsidiary of Canada Drugs, Ltd. Canada Drugs is an internet based pharmacy corporation located in Winnipeg, Manitoba, Canada. Rockley Ventures paid Bottomley \$5 million for MHCS. Canada Drugs, Rockley Ventures, and the related companies retained Bottomley's company's name, website and domain name, any stock on hand, and his physician distribution list. The companies continued to solicit and distribute to Bottomley's previous customers using his company's name and letter head.

Bottomley was also to remain as an advisor to Rockley Ventures, Canada Drugs and related companies following the sale of MHCS. Bottomley was paid \$10,000 per month for his advisory services by the companies. In his advisor capacity, Bottomley occasionally made sales calls to physicians and dealt with shipment and payment issues. On one occasion, Bottomley traveled to Tennessee, on behalf of Canada Drugs and its related companies, to work with Volunteer Distribution

on their mail-order shipping of pharmaceuticals on behalf of the companies. In January of 2012, American officials were notified by the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom, that potential counterfeit oncology drugs known as Avastin® (marketed in Turkey as Altuzan) had been identified and shipped to the United States. The United Kingdom wholesaler shipped 41 of the identified packs of Avastin® to Volunteer Distribution, a company located in Gainesboro, Tennessee. Volunteer Distribution had a pharmaceutical distribution contract with QSP, a subsidiary company of Canada Drugs. Volunteer Distribution received oncology drugs with the understanding that they would ship those drugs to clients once they were provided with a client and packing list. The packing list also included “Montana Healthcare Solutions” in the upper left-hand corner with a symbol associated with MHCS.

Lab analysis of the Avastin® determined the drug to be counterfeit – the substance seized and tested did not contain any of the active drug ingredient bevacizumab that is found in legitimate versions of Altuzan and Avastin®. It was determined that Volunteer Distribution had already shipped 36 of the 41 packs of Avastin® to

American physicians for use with patients. The 5 remaining packs of the counterfeit Avastin® were shipped back to the United Kingdom wholesaler.

SENTENCING RECOMMENDATION

The defendant has requested that the Court vary from the advisory guideline range recommended by the government of 10 to 16 months and impose a sentence of probation. The defendant has based his argument for a variance in large part on the § 3553(a) factors. In an effort to address all of the defendant's arguments, each of the § 3553(a) factors will be addressed in turn. The United States believes that a fair assessment of the advisory guideline calculation, the 18 U.S.C. § 3553(a) factors and relevant case law support a sentence of 12 months and a day incarceration for the defendant in this matter.

I. The nature and circumstances of the offense and the history and characteristics of the defendant.

Bottomley engaged in a "business" to make a profit. His business, no matter how well meaning, was operated in circumvention of American laws, particularly the FDCA. While it is not the

government's intention to take a side on the highly controversial issue of the pricing of prescription drugs in the United States versus the rest of the world, what is clear is that the closed system of distribution within the United States offers a layer of protection to the citizens of the United States that is stripped away by the activities of individuals like Bottomley and entities like Canada Drugs and Rockley Ventures.

In discussions about the topic of misbranded or adulterated prescription drugs it is hard to get the general public too excited when they see a cost savings from ordering from online pharmacies that market foreign versions of approved products. However, this case in particular demonstrates the dangers associated with such business practices. In this case, there was counterfeit Avastin – a life saving chemotherapy drug – that was not much more than saline solution. The counterfeit is the worst case scenario in any of these types of cases and the risk that such companies choose to take when sourcing their products from facilities and distributors not approved by the FDA.

The nature and circumstances of the crime must be considered when determining an appropriate sentence, but as the defendant noted in his own sentencing memorandum, not in a vacuum. This case is

about greed, the greed of the distributors like Bottomley and Canada Drugs, as well as the physicians who purchased discounted, foreign drugs for distribution to citizens suffering from cancer and other serious ailments. The only true loser in this case was the patient at the end of the distribution chain who unfortunately received saline solution instead of life saving chemotherapy drugs.

To be fair, at the point at time that the counterfeit Avastin was distributed Bottomley was but a cog in the wheel at Canada Drugs, but it is the same sort of business practice he engaged in that put patients at risk in the first place. As much as the proverbial government red tape can be an inconvenience, it is the same red tape that offers Americans a closed system of distribution which limits the risks associated with the drugs we consume and the sources of such drugs. Those like Bottomley that engage in a gray market of pharmaceutical distribution are playing Russian roulette with the health of the American public. Such a risk cannot be ignored and should be a fundamental concern when determining an appropriate sentence for the defendant.

Moving to the defendant's specific history and characteristics, the government cannot disagree with the defense, Bottomley, up until his charges in this case has not had any prior contacts with the law. However, Bottomley did operate MHCS from 2008 to 2010, despite receiving notice in 2008 from the FDA that one of his shipments was returned at the border as well a person visit from an FDA inspector around the same time period. Despite the two contacts, Bottomley continued to operate his business and then sold the company for a healthy sum – \$5million. Bottomley is a criminal history category I, and as such finds himself with a lower advisory guideline range. The fact that Bottomley has no prior criminal history has been adequately taken into account by the advisory guideline calculation and it should be entitled to no further weight when arriving at an appropriate sentence in this case.

The defense's assessment of Bottomley's cooperation from his first contact with law enforcement is correct – Bottomley has sought to assist law enforcement at every request. The details of such cooperation are set forth in the government's sealed motion pursuant to U.S.S.G. § 5K1.1. The United States stands by the recommendation of

a one level reduction based in large part on the reduced charge the defendant was permitted to plead to because of his pre-charging cooperation with the United States.

Part of viewing this case as a whole includes the financial side of the equation. At this point, the United States has stripped Bottomley of most of the gains he made by selling his company to Canada Drugs. The United States seized, and has now forfeited, \$1,088,378.17 in cash, a 2011 Aston Martin/Vantage V-12 and ten parcels of land valued at over \$3million. PSR ¶ 28. The forfeiture of cash and property has largely divested Bottomley of any profit associated with MHCS and its sale to Canada Drugs. Based on the total nature of the forfeiture the United States is not advocating for a fine in this matter.

Paul Bottomley is not a bad person. After interacting with him on several occasions it is fair to say that he is a nice guy. What cannot be ignored, because he is a “nice guy”, is the conduct Bottomley readily engaged in and profited from all at the potential risk of the end users – cancer patients. The nature and circumstances of the offense and the specific characteristics of the defendant support a sentence within the

advisory guideline range of 10 to 16 months and the United States requests a sentence of 12 months and a day incarceration.

II. The need for the sentence imposed to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense.

The government is not asking for a pound of flesh, only what the many factors the Court is now tasked with analyzing support, a sentence within the advisory guideline range. This is a serious offense. An offense that involved thought and deliberation – conscious choices were made by Bottomley along the way that led him to the path he now walks.

The FDCA is not a government obligation that keeps our drug prices higher than the rest of the world, it is the system by which our pharmaceutical goods are delivered in a safe and effective manner. In instances of counterfeit or contamination the system in the United States allows for quick identification and notification to any potentially affected patients. The gray market in which Bottomley and Canada Drugs operated denies patients the safety check held in place by the FDCA. The sentence imposed by the Court must take into account the importance of and promote respect for the FDCA.

What is just punishment? It is a question often wrestled with by prosecutors and defense attorneys and then handed off to the Courts. The question really is what is sufficient but not greater than necessary to satisfy all of the factors previously outlined. In this case, based on the conduct and this defendant's characteristics, justice is served by a sentence of 12 months and a day incarceration.

III. The need for the sentence imposed to afford adequate deterrence to criminal conduct.

Normally, it is difficult to argue to the Court that any one case will afford general deterrence, however, this may be the rare case where a sentence imposed by the Court not only sends a very specific message to the defendant but also to the general public. In this instance, this case is being watched by those waiting to pick up the mantle of MHCS and other international companies to continue to distribute misbranded, adulterated and counterfeit pharmaceuticals to the citizens of the United States – primarily because it is an incredibly lucrative business. The sentence imposed in this case will have the potential to send a message of general deterrence to the public.

IV. The need for the sentence imposed to protect the public from further crimes of the defendant.

It is the government's hope that Bottomley has learned his lesson through this experience. In the event that he attempts to engage in such business practices again, his public exposure at this point will make any anonymity in the industry incredibly difficult.

V. The need for the sentence imposed to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

Mr. Bottomley is an educated man in good health. Incarceration as part of the sentence is purely a punishment and deterrence issue. The United States believes that the facts and circumstances of this case necessitate a period of incarceration.

VI. The kinds of sentences available.

The defendant's current guideline range is in Zone C of the advisory guidelines. Probation is not an option if the Court stays within Zone C of the advisory guidelines. However, should the Court vary as requested by the defense the United States requests at a minimum that a split sentence be imposed. Incarceration, preferably

12 months and a day, is necessary to ensure deterrence and punishment are met.

VII. The kinds of sentence and the sentencing range established for the applicable category of offenses committed by the applicable category of defendant as set forth in the guidelines.

The United States has no objection to the advisory guideline calculation found in the presentence report but respectfully seeks a one level departure pursuant to the 5K1.1 motion previously filed.

VIII. The need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct.

As was previously noted in the government's 5K1.1 motion, there are two similar cases which demonstrate the types of sentences imposed where individuals run afoul of the FDCA and the gray market of pharmaceutical distribution. In the case of Andrew Strempler, he operated an internet pharmacy known as RXNorth.com. Strempler was charged with conspiracy to commit mail fraud for sending misbranded and adulterated drugs into the United States. Strempler would actually replace the labels on the products he shipped so they appeared to be from Canada as opposed to the actual country of origin. See

United States of America v. Andrew Strempler, Case No.

11-20385CR-Martinez (S. Dist. Florida). Strempler hid out in Panama after an indictment was returned and was extradited and pled guilty. Strempler was sentenced to 48 months in prison and a \$300,000 fine.

In a case more closely related, James R. Newcomb was charged in Missouri with conspiracy to distribute adulterated prescription drugs to physicians in the United States. Bottomley previously worked for Newcomb before he began MHCS. See *United States v. James R. Newcomb*, Case. No. 4-12-CR-0009 RWS DDN (E. Dist. of Missouri). Newcomb was facing an advisory guideline range of 33 to 41 months and was sentenced to 24 months imprisonment and ordered to forfeit his interest in \$1.4million that was seized during the investigation.

In comparison, Bottomley is facing a far shorter sentence because he was given a benefit for his cooperation pre-charging. Bottomley did not plead to a conspiracy count in which his advisory guideline range would have been catapulted by the amount of money involved under U.S.S.G. § 2B1.1, instead, because of the charge he was capped at a total offense level of 19. See PSR ¶ 34. Bottomley has been rewarded for his cooperation before he was charged and now after he was charged

based on the government's filing of a § 5K1.1 motion. The United States is asking for a sentence of less than half of what Newcomb received for his involvement in a similar business, the business Bottomley worked for prior to starting his own company. The recommended sentence would ensure there was not disparity between similarly situated defendants as well as ensuring just punishment in this case based on these facts.

CONCLUSION

The defendant, Paul Daniel Bottomley, made a series of decisions that placed Americans at risk. The risk was weighed and measured against the potential profit. Bottomley has done all he can to date to atone for his actions but the sentence imposed must serve to do more than simply punish this defendant. The sentence imposed must deter, punish, promote respect for the law and educate the United States, and in fact the world community, that a cheaper bottom line is unacceptable when the health of American citizens is at stake. A sentence of 12 months and one day will ensure the goals of sentencing in the federal system are met.

DATED this 9th day of July, 2013.

MICHAEL W. COTTER
United States Attorney

/s/ Jessica T. Fehr

JESSICA T. FEHR
Assistant U.S. Attorney